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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/815,393 | 03/22/2001 | David N. Krag | 34114-8001US1 | 5450 |

25096 7590 06/19/2002

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EXAMINER

BAXTER, JESSICA R

ART UNIT PAPER NUMBER

3731

DATE MAILED: 06/19/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/815,393

Applicant(s)

Krag, David N.

Examiner

Jessica R Baxter

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 32-36 and 65-97 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 83-87 and 92-97 is/are allowed.
- 6) ☒ Claim(s) 32-36, 65-68, 74-76, 82, 88 and 91 is/are rejected.
- 7) ☒ Claim(s) 69-73, 77-81, 89 and 90 is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 22 March 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

DETAILED ACTION

Specification

1. The disclosure is objected to because of the following informalities:

On page 11 line 5, change "adjustment 62" to --adjustment 66--.

Appropriate correction is required.

Information Disclosure Statement

2. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Drawings

3. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they do not include the following reference sign(s) mentioned in the description: "112" and "114". A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 34, 79, 94 and 95 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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6. Claim 34 recites the limitation "said outside diameter" in line 1. There is insufficient antecedent basis for this limitation in the claim. It is unclear what diameter the claim is referring to.
7. Claim 79 recites the limitation "the elongate member" in line 3. There is insufficient antecedent basis for this limitation in the claim.
8. Method claims 94 and 95 depend upon apparatus claim 92. It is apparent that these claims should depend upon claim 93. The claims have been examined as if they were dependent upon claim 93.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

10. Claims 32, 35, 65, 66, 67, 75, 76 and 82 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,509,900 to Kirkman.

Regarding claim 32, Kirkman discloses a device comprising an elongate tube (see FIG 22 introducer sheath 148) having a central bore and an aperture adjacent the distal end (see FIG. 22 distal end of sheath 148), an elongate member with at least one anchor member attached (see FIG. 8

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wire 12 and tip retainer 9), and the anchor member projects through the aperture and extends transversely (see Column 18 lines 17-51).

Regarding claim 35, Kirkman discloses that at least one anchor member includes four anchor members (see FIG. 2A tip retainer 9).

Regarding claim 65, Kirkman discloses that each anchor member is associated with an aperture (see FIG. 2B openings 40).

Regarding claim 66, Kirkman discloses that each anchor member projects from its associated aperture (see FIG. 2B).

Regarding claim 67, Kirkman discloses a barb adjacent an end of at least one tissue anchor (see FIG. 2A prong 26).

Regarding claim 75, Kirkman discloses a device comprising an elongate tube having a central bore (see FIG. 2A lumen 28) and a plurality of apertures (see FIG. 2A openings 40), a manually controllable actuator (see Column 12 lines 41-48), and a plurality of manually deployable anchor members (see FIG. 2A wires 12). Each anchor member is associated with its own aperture (see FIG. 2A openings 40) and is connected to the actuator.

Regarding claim 76, Kirkman discloses the apertures are spaced proximally of the distal end (see FIG. 2A openings 40).

Regarding claim 82, Kirkman discloses that each anchor member projects from its associated aperture when the actuator is in its first position (see FIG. 2A).

11. Claims 32, 35, 36, 67, 68, 74, 88 and 91 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,059,734 to Yoon.

Regarding claim 32, Yoon discloses a device comprising comprising an elongate tube (see FIG. 11 needle 112) having a central bore and an aperture adjacent the distal end (see FIG. 11 distal

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end of needle 112), an elongate member (see FIG. 11 anchoring device 142) with at least one anchor member attached (see FIG. 11 tongs 148), and the anchor member projects through the aperture and extends transversely (see FIG. 11 tongs 148).

Regarding claim 35, Yoon discloses that at least one anchor member includes four anchor members (see FIG. 11 tongs 148).

Regarding claim 36, Yoon discloses that the anchor members have a curved configuration (see FIG. 11 tongs 148).

Regarding claim 67, Yoon discloses that the anchor member include barbs adjacent the end 9 (see FIG. 11 tongs 148).

Regarding claim 68, Yoon discloses that the elongate tube is adapted to be advanced into a volume of tissue (see FIG. 19 distal end 116 and Column 12 lines 54-57).

Regarding claim 74, Yoon discloses that the elongate member is sized for a close sliding fit within the central bore of the elongate tube (see FIG. 18 needle 112 and anchoring device 142).

Regarding claim 88, Yoon discloses a method for stabilizing tissue mass using his device. Yoon discloses that the method comprises the steps of advancing the distal end of the tube into the tissue and advancing the rod and forcing the anchor members outward (see FIG. 21 and 22 and Column 12 lines 54-57 and Column 13 lines 44-53).

Regarding claim 91, Yoon discloses a method for removing a tissue mass comprising advancing the distal end of the elongate tube, advancing the rod distally, and stabilizing the tissue with the anchor members, and removing the tissue mass (see Column 12 lines 54-57 and Column 13 lines 44-53).

12. Claims 32, 35, 36, 65, 67 and 74 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,936,823 to Colvin et al.

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Regarding claim 32, Colvin discloses a device comprising an elongate tube (see FIG. 1 body member 12) having a central bore (see FIG. 1A bore 22) and an aperture adjacent the distal end (see FIG. 1 slot 16), an elongate member (see FIG. 2 stem 20) with at least one anchor member attached (see FIG. 1 arm members 18), and the anchor member projects through the aperture and extends transversely (see FIG. 2 arm members 18 and slot 16).

Regarding claim 35, Colvin discloses that the at least one anchor member includes four anchor members (see FIG. 1 arm members 18).

Regarding claim 36, Colvin discloses that at least one anchor member has a curved configuration (see FIG. 2 arm members 18).

Regarding claim 65, Colvin discloses that the at least one aperture includes four apertures (see FIG. 1 slot 16).

Regarding claim 67, Colvin discloses that at least one anchor member includes a barb adjacent its distal end (see FIG. 1 arm members 18).

Regarding claim 74, Colvin discloses that a portion of the elongate member is sized for a close sliding fit with the central bore of the elongate tube (see FIG. 3).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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14. Claims 33 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Yoon '734. Yoon discloses the claimed invention except for the size. It would have been an obvious matter of design choice to change the size, since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art.

Allowable Subject Matter

15. Claims 83-87 and 92-97 are allowed.

16. Claims 69-73, 77-81 and 89-90 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

17. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

The following patents are cited to further show the state of the art with respect to tissue grasping devices:

U.S. Patent No. 4,393,872 to Reznik et al.

U.S. Patent No. 4,909,789 to Taguchi et al.

U.S. Patent No. 4,994,079 to Genese et al.

U.S. Patent No. 5,910,144 to Hayashi

U.S. Patent No. 5,707,390 to Bonutti

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jessica R Baxter whose telephone number is 703-305-4069. The examiner can normally be reached on M-F 8:30AM - 5:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Milano can be reached on 703-308-2496. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3590 for regular communications and 703-305-3590 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



Jessica R Baxter
Examiner
Art Unit 3731

jrb
June 13, 2002



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